REMARKS

Claims 38-74 are pending in this application. Claims 43, 48, 60 and 72 have been amended. Claim 38 is independent. Claims 1-37 have been canceled by a previous Amendment. Reconsideration of this application, as amended, is respectfully amended.

Objection to the Specification

The specification stands objected to for various informalities. As the Examiner will note, a substitute specification has been provided for the Examiner's consideration. Applicants respectfully submit that the Specification includes no new matter and includes the changes as indicated on the attached comparison version of the specification.

In addition, as the Examiner will note, the substitute specification contains an Abstract of the Disclosure on a separate sheet. Furthermore, paragraphs [0063] and [0064] of the substitute specification have been added to describe Figs. 9-14 in order to provide proper antecedent basis for claims 46 and 63 as required by the Examiner.

In view of the above, Applicants respectfully submit that the specification objection has been obviated. Accordingly, reconsideration and withdrawal of the specification objection are respectfully requested.

Objection to the Drawings

The drawings stand objected to under 37 CFR 1.83(a) since the drawings do not show every feature of the invention specified in the claims.

As the Examiner will note, Figs. 9-14 have been added for the Examiner's consideration. Fig. 9 illustrates a connecting section 15a having a roughened surface which is at least partly a blasted surface (claim 45). Fig. 10 illustrates a connecting section 15b having a roughened surface 15 which is at least partly provided with a circumferentially oriented roughness in the form of circumferential beads that have a height less than that of the screw thread profiles of the first and second cylindrical sections and no greater than 0.3 mm (claims 47-48). Figs. 11 and 12 illustrate a connecting section 15c having a roughened surface which is at least partly provided with a circumferentially oriented roughness in the shape of a screw thread profile which has a height less than that of the screw thread profiles of the first and second cylindrical sections and no greater than 0.3 mm (claims 47-48). Fig. 13 illustrates a proximal section which is provided with a roughness 18a in the form of circumferential beads (claim 64). Fig. 14 illustrates a connecting section 15d having a roughened surface which is at least partly provided with a circumferentially oriented roughness in the shape of a screw thread profile that has

a height essentially the same as that of the screw thread profiles of the first and second cylindrical sections.

In view of the above amendments and remarks, Applicants respectfully submit that the drawing objection has been obviated. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

Objection to the Claims

Claims 43, 60 and 72 stand objected to for minor informalities. As the Examiner will note, claims 43, 60 and 72 have been amended, taking into consideration the specific deficiencies pointed out by the Examiner. Applicants respectfully submit that claims 43, 60 and 72 are now in proper form. Accordingly, reconsideration and withdrawal of the Examiner's claim objection are respectfully requested.

Rejection Under 35 USC §112

Claims 48, 60 and 61 stand rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. This rejection is respectfully traversed.

As the Examiner will note, claims 48 and 60 have been amended, taking in consideration the specific deficiencies pointed out by the Examiner. Applicants respectfully submit that claims 48, 60 and 61 are now definite and clear. Accordingly, reconsideration and withdrawal of the Examiner's rejection under 35 USC §112, second paragraph, are respectfully requested.

Obviousness/Double Patenting

Claims 38-74 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 36-70 of copending application 10/089,864. This rejection is respectfully traversed.

As the Examiner will note, a Terminal Disclaimer has been provided for the Examiner's consideration. This Terminal Disclaimer has been filed in order to expedite prosecution and should not be considered to be an acquiescence of the Examiner's rejection. Applicants respectfully submit that the Terminal Disclaimer obviates the Examiner's obvious-type double patenting rejection. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

Rejection Under 35 USC §§102 and 103

Claims 38-42, 44-55, 67, 73 and 74 stand rejected under 35 USC §102(b) as being clearly anticipated by Albrecktsson et al. (WO

97/25939). Claims 38, 39, 55-61, 63, 67 and 73 stand rejected under 35 USC §102(b) as being clearly anticipated by Rambert et al. (GB 2 033 755). Claims 38, 52-54 and 67 stand rejected under 35 USC §102(b) as being clearly anticipated by Vrespa (US Patent 5,593,410). Claims 38, 52-54 and 56-67 stand rejected under 35 USC §102(b) as being anticipated by Hansson et al. (US Patent 5,588,838). Claims 38, 40-50, 52-54, 67 stand rejected under 35 USC §102(e) as being clearly anticipated by Kaneko (US Patent 5,863,167). Claims 56-66 stand rejected under 35 USC §103(a) as being clearly unpatentable over Albrektsson et al. in view of Hansson et al. Claims 68-72 stand rejected under 35 USC §103(a) as being unpatentable over Albrektsson et al. in view of Sotereanos (US Patent 6,284,002). These rejections are respectfully traversed.

The present invention is directed to a femur fixture for a hip-joint prosthesis, wherein a combination of elements is recited including "a relatively short frusto-conical proximal section at the proximal end, and a proximal cylindrical section having a screw thread profile thereon and extending towards the distal end from the frusto-conical proximal section." Applicants respectfully submit that the references relied on by the Examiner fail to teach or suggest the presently claimed invention.

In particular, WO 97/25939 (Albrektsson et al.) describes a fixture for a hip joint prosthesis. Figure 2 of Albrektsson et al. illustrates a cross-section of the fixture and is reproduced below.

The fixture comprises a threaded cylindrical peripheral surface 6 to be inserted into the human femur. A circumferential flange 3 limits the insertion of the fixture by abutting against a cut surface of the femur. However, as is clearly seen in Figure 2, the portion interconnecting the circumferential flange 3 and the cylindrical peripheral surface 6 is a clearly concave portion and not a frusto-conical shape as claimed in independent claim 38 of the present application. This difference is supported by the Merriam-Webster dictionary, which describes a cone as "*a solid generated by rotating a right triangle about one of its legs*". This definition cannot be applied to the shape of the portion interconnecting the circumferential flange 3 and the cylindrical peripheral surface 6 in Albrektsson et al., which forms a clearly concave rotational surface. Consequently, Albrektsson et al. fails to disclose a "frusto-conical proximal section" as recited in independent claim 38 of the present invention.

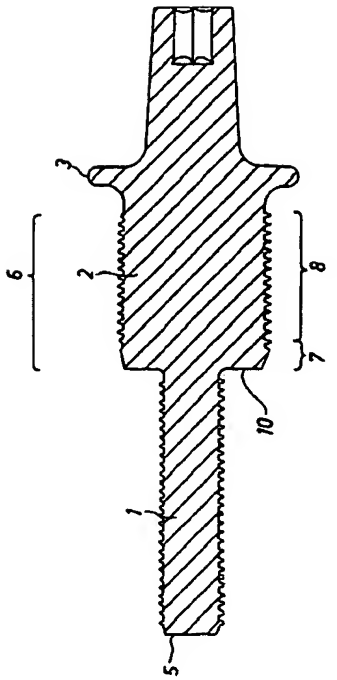


Fig. 2

Referring to page 6, lines 1-4 of the Examiner's Office Action, the Examiner considers the concave portion between the flange 3 and the fixture member 2 to be the frusto-conical proximal section recited in independent claim 38 of the present invention. However, the concave portion is formed by a curved surface over an entire length thereof. In view of this, there is no portion of the concave portion that is formed by a solid generated by rotating a right triangle about one of its legs as required by the term "frusto-conical" recited in independent claim 38 of the present invention. Accordingly, the Albrektsson et al. reference fails to anticipate independent claim 38 of the present invention.

The frusto-conical proximal section according to the present invention has a superior ability to distribute loads to the cortical bone as described on page 2, line 33 - page 3, line 2 of

the present application, thereby solving the problems discussed on page 1 of the present application. The frusto-conical shape of the proximal section reduces possible load variations in the axial direction as well as in the lateral direction of the fixture. A transition in the curved shape of Albrektsson et al. cannot provide for a load distribution as even as the frusto-conical proximal section of the present invention. On the contrary, in Albrektsson et al. the load perpendicular to the surface is instead exponentially increasing or decreasing along the curved shape depending on the original direction of the load, and likewise the loads parallel with the surface will also exponentially increase or decrease along the curved shape. This in turn causes irregularly distributed stresses in the cortical bone, which affects the stability of the fixture inside the bone.

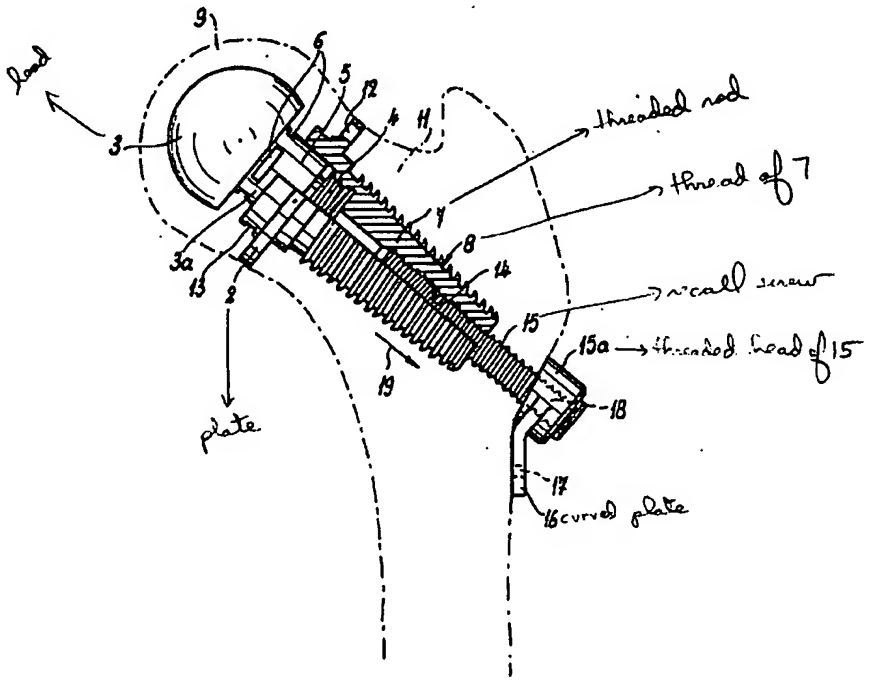
Also, Albrektsson et al. does not address the problem with the lack of loading of the cortical bone caused by the step between the circumferential flange 3 and the cylindrical peripheral surface 6. There is therefore nothing in this document which would encourage the one having ordinary skill in the art to modify the configuration of the fixture so as to obtain a femur fixture with a frusto-conical proximal section according to independent claim 38 of the present invention which solves said problem. Furthermore, one having ordinary skill in the art would have no incentive to modify the fixture of Albrektsson et al. after having consulted any

other of the now (or previously) cited documents, since none of these documents have identified the drawback related to a lack of loading the cortical bone.

In view of the above, Applicants respectfully submit that independent claim 38 is not anticipated or rendered obvious over the Albrektsson et al. reference relied on by the Examiner. Accordingly, reconsideration and withdrawal of the Examiner's rejection in view of the Albrektsson et al. reference are respectfully requested.

With regard to the GB 2 033 755 A (Rambert et al.) reference, this reference describes a hip joint prosthesis, its only figure being reproduced below. The prosthesis comprises a threaded rod 7 and a recall screw 15. The threaded rod 7 extends from a plate 2 and a spherical head 3 through the spongy cancellous bone of the femur. The threaded rod 7 has according to the figure an axial extension corresponding to well over half the length of the portion anchoring the bone. When comparing the lengths of the threaded rod 7 and the recall screw 15, the figure gives that the length of threaded rod 7 is between two and three times the length of the exposed portion of the recall screw 15. In this perspective, Applicants respectfully object to the Examiner's opinion that the threaded rod 7 can be regarded as a relatively short frusto-conical section. The threaded rod 7 is not "relatively short" in relation to the recall screw 15, and is not "relatively short" in relation to

the intraosseous anchoring structure as a whole. Applicants also submit that the recall screw 15 cannot be regarded as a proximal cylindrical section, since the recall screw 15 in fact is much closer positioned to the distal end than the proximal end. Since the Rambert et al. reference fails to disclose the "relatively short frusto-conical proximal section" and the "proximal cylindrical section" as recited in independent claim 38 of the present invention, Applicants submit that the Rambert et al. reference fails to anticipate independent claim 38 of the present invention.



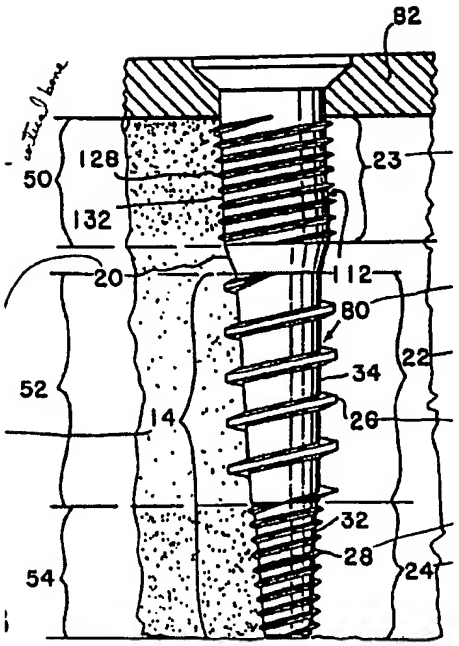
Further to the above, Applicants submit that there is no resemblance between the functions of the threaded rod with the recall screw and the frusto-conical proximal section with the proximal cylindrical section according to the present invention,

since the former are not to bear against the cortex of the femur neck but are mainly to be surrounded by spongy cancellous bone. Also, Rambert et al. do not address the problem with the lack of loading of the cortical bone caused by the step between the collar section and the proximal cylindrical sections. Instead the relatively long conical shape of the threaded rod in Rambert et al. has the function of enabling a more rapid placement, since the long conical shape makes it possible to almost totally introduce the rod without screwing (see page 2, lines 15-21). Thus, the long conical shape of the Rambert et al. rod is clearly different from the frusto-conical proximal section as regards both structure and function. There is therefore nothing in this document which would encourage one having ordinary skill in the art to modify the configuration of the fixture so as to obtain a femur fixture according to independent claim 38 of the present invention.

In view of the above, Applicants respectfully submit that independent claim 38 is not anticipated or rendered obvious over the Rambert et al. reference relied on by the Examiner. Accordingly, reconsideration and withdrawal of the Examiner's rejection in view of the Rambert et al. reference are respectfully requested.

With regard to the US 5,593,410 (Vrespa) reference, this reference describes a general screw device for fixing a prosthesis, such as a plate, to the outside of a bone. The screw device

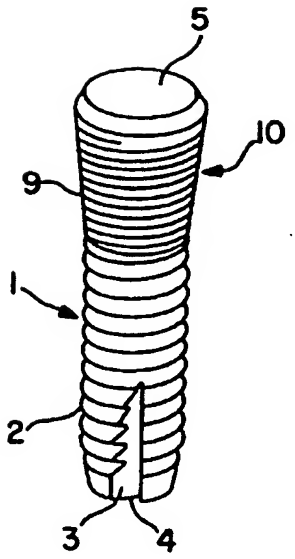
comprises according to Figure 8 (reproduced below) an anchoring structure comprising an alleged frusto-conical proximal section being a part of the screw head at the proximal end, a threaded shrank 23 and a threaded shrank 14. According to claim 38 of the present invention, the femur fixture comprises "an intraosseous anchoring structure," i.e. a structure which is to be anchored in bone. Furthermore, according to independent claim 38, the intraosseous anchoring structure has i) a proximal end, ii) a distal end, iii) a relatively short frusto-conical proximal section, and iv) a proximal cylindrical section. Thus, the features i-iv form part of the intraossous anchoring structure, i.e. they are parts to be anchored in bone. In the screw of US 5,593,410 only the shanks 23 and 14 are inserted into bone, i.e. only these shanks form part of the intraosseous anchoring structure of Vrespa. It can clearly be seen that the proximal end, the alleged frusto-conical proximal section and a portion of the threaded shrank 23 are positioned outside of the bone in a counter-acting element 82 and they do not form part of an intraosseous anchoring structure. Since the Vrespa reference fails to disclose a frusto-conical proximal section that is a part of an intraosseous anchoring structure as recited in independent claim 38 of the present invention, Applicants respectfully submit that the Vrespa reference fails to anticipate independent claim 38.



In contradiction to the opinion of the Examiner, the alleged frusto-conical proximal section of the screw head according to the referred Figure 8 is not to bear against the cortical portion of the bone, but to bear directly against a counter-acting element 82. Also, Vrespa does not address the problem with the lack of loading of the cortical bone caused by the step between a collar section and a proximal cylindrical sections of a femur fixture. There is therefore nothing in this document which would encourage one having ordinary skill in the art to modify the configuration of the general bone screw device so as to obtain a femur fixture with a frusto-conical proximal section comprised in an intraosseous anchoring structure according to independent claim 38 of the present invention.

In view of the above, Applicants respectfully submit that independent claim 38 is not anticipated or rendered obvious over the Vrespa reference relied on by the Examiner. Accordingly, reconsideration and withdrawal of the Examiner's rejection in view of the Vrespa reference are respectfully requested.

With regard to the US 5,588,838 (Hansson et al.) reference, this reference describes a dental fixture (Fig. 1 reproduced below) having a conically flaring portion 10 and a generally cylindrical body 1. Hansson et al. does not disclose a femur fixture. There is a considerable difference in purpose and dimension between the present invention and the disclosed dental fixture of Hansson et al. While the dental fixture is only a few millimeters long and aimed to support an even smaller dental abutment, the femur fixture exceeds the size of the dental fixture considerably. In other words, there is a clear inherent structural difference, in terms of size, between a dental fixture and a femur fixture. It is thus by no means possible to use the dental fixture in femur applications. Applicants respectfully submit that the positive recitation of a femur fixture in independent claim 38 of the present invention clearly defines claim 38 over the dental fixture of Hansson et al. Accordingly, Hanson et al. fails to anticipate independent claim 38 of the present invention.

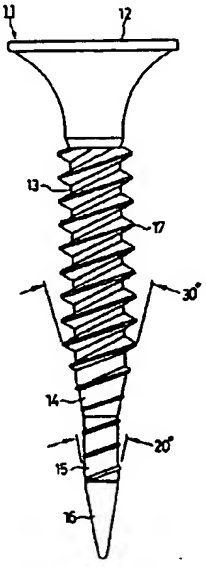


Furthermore, the dental fixture of Hansson et al. does not disclose any suitability for use with a femur fixture; there is for example no indication of any possible connection of a femur prosthesis to the conically flaring portion of the dental fixture. Imagine a dental fixture having a length of half an inch and a width of a tenth of an inch connected to a prosthesis having a diameter of several inches. Additionally, there is no addressing of the problem with the lack of loading of the cortical bone caused by the step between the collar section and the proximal cylindrical sections of a femur fixture.

In view of the above, Applicants respectfully submit that independent claim 38 is not anticipated or rendered obvious over the Hansson et al. reference relied on by the Examiner. Accordingly, reconsideration and withdrawal of the Examiner's

rejection in view of the Hansson et al. reference are respectfully requested.

With regard to the US 5,863,167 (Kaneko) reference, this reference describes a drilling screw for fixing gypsym boards to thin steel plates (Figure 1 reproduced below). No application in relation to femur fixtures is disclosed. The screw head comprises a trumpet section 12 with a curved shape that is intended to be forced into the material without previously having provided any countersunk bore in the material. Following the argument about definition of frusto-conical shape, Applicants submit that the trumpet section 12 of the screw head is not a frusto-conical proximal section as recited in independent claim 38 of the present invention. Accordingly, Kaneko fails to anticipate independent claim 38 of the present invention.



Furthermore, the drilling screw does not disclose any suitability for use with a femur fixture. Additionally, there is no addressing of the problem with the lack of loading of the cortical bone caused by the step between the collar section and the proximal cylindrical sections of a femur fixture.

In view of the above, Applicants respectfully submit that independent claim 38 is not anticipated or rendered obvious over the Kaneko reference relied on by the Examiner. Accordingly, reconsideration and withdrawal of the Examiner's rejection in view of the Kaneko reference are respectfully requested.

With regard to dependent claims 39-74, Applicants respectfully submit that these claims are allowable due to their dependence on independent claim 38, as well as due to the additional recitations in these claims.

In view of the above amendments and remarks, Applicants respectfully submit that claims 38-74 clearly define the present invention over the references relied on by the Examiner. Accordingly, reconsideration and withdrawal of the Examiner's rejections under 35 U.S.C. §§ 102 and 103 are respectfully requested.

Conclusion

Since the remaining references cited by the Examiner have not been utilized to reject the claims, but to merely to show

the state of the art, no further comments are deemed necessary with respect thereto.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number of (703) 205-8000, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

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PCL/mlr
0104-0389P

Attachment(s): Five (5) sheets of Drawings
Terminal Disclaimer
Substitute Specification
Marked-Up Specification

(Rev. 02/12/2004)

FEMUR FIXTURE AND SET OF FEMUR FIXTURES

Field of the Invention

[0001] The present invention relates to a femur fixture for a hip-joint prosthesis comprising an intraosseous anchoring structure of a generally circular cross-section adapted for screwing laterally into a complementary bore drilled laterally into the neck of a femur after resection of the femur head to an anchored position. The invention also relates to a set of such femur fixtures.

Background of the Invention

[0002] A femur fixture of the aforementioned type is disclosed in Applicant's prior International patent application publication WO93/16663. In this femur fixture the intraosseous structure has a screw threaded cylindrical section at the proximal end. The use of a cylindrical proximal section in the intraosseous structure of the femur fixture of WO93/16663 enables the threads thereon to engage with the cortex of the femur neck and increase the fixation strength of the femur fixture in the femur. However, the threads at the terminal proximal section of the cylindrical section do not register in the medial cortex of the femur neck at the resected surface. This is due to the cortex of the femur neck flaring outwardly adjacent the resected surface.

[0003] This lack of loading of the cortex at the resected surface of the femur by the intraosseous anchoring structure of the femur fixture can lead to bone resorption at the resected surface. This situation is not able to be simply addressed by increasing the diameter of the cylindrical proximal section of the intraosseous anchoring structure of the WO93/16663 femur fixture since it would result in the threads of the cylindrical proximal section puncturing

the cortex in the body of the femur neck or being dangerously close to puncturing the cortex due to the trumpet-like shape of the cortex in the femur neck.

Summary of the Invention

[0004] Thus, the object of the present invention is to provide an improved femur fixture where the above mentioned drawback is addressed.

[0005] This and other objects are achieved according to the present invention by providing a femur fixture having the features defined in the independent claim. Preferred embodiments are defined in the dependent claims.

[0006] According to the present invention there is provided a femur fixture for a hip-joint prosthesis, comprising an intraosseous anchoring structure of a generally circular cross-section for screwing laterally into a complementary bore drilled laterally into the neck of a femur after resection of the femur head to an anchored position. The intraosseous anchoring structure has a proximal end, a distal end, a relatively short frusto-conical proximal section at the proximal end, and a proximal cylindrical section having a screw thread profile thereon and extending towards the distal end from the frusto-conical proximal section, the frusto-conical proximal section and the proximal cylindrical section each being dimensioned so as to bear against the cortex of the femur neck when the intraosseous anchoring structure is in the anchored position.

[0007] Thus, the present invention is based on the advantageous idea of providing a femur fixture of the above-mentioned type with a relatively short frusto-conical proximal section at the proximal end of the intraosseous anchoring structure.

[0008] The provision of a relatively short frusto-conical proximal section at the proximal end of the intraosseous anchoring structure thus loads the cortex of the femur neck adjacent

the resected surface and the proximal cylindrical section loads the cortex in the body of the femur neck. Thereby, an improved anchorage of the femur fixture in the femur of the patient can be obtained.

[0009] The frusto-conical section preferably has a flank angle in the range of 8-15°, preferably in the range 10-13°, even more preferably approximately 12°.

[0010] According to preferred embodiments of the invention the frusto-conical section has an axial extent in the range of 5-10 mm. Preferably, the axial extent is approximately 8 mm.

[0011] Advantageously, the proximal end of the frusto-conical proximal section has a diameter in the range of 18-30 mm.

[0012] Advantageously, the distal end of the frusto-conical proximal section, i.e. the end interfacing the proximal cylindrical section, has essentially the same diameter as the proximal cylindrical section. Thus, there will be no sharp edges in the transition area between the frusto-conical proximal section and the proximal cylindrical section that could induce undesired stresses.

[0013] According to preferred embodiments of the invention the frusto-conical section has at least partly a roughened surface. This improves the integration of the frusto-conical section with the cortex (termed "osseointegration" in the art). The roughening may be achieved by grit blasting, etching or machining, or by a combination of one or more of these roughening techniques.

[0014] Alternatively or additionally, the frusto-conical proximal section could be provided with a circumferentially oriented roughness, preferably machined. Such circumferentially oriented roughness could for instance be provided in the form of grooves, beads, tracks, or screw threads. The provision of such a circumferentially oriented roughness would im-

prove the short term anchorage capacity of the intraosseous anchoring structure due to the engagement of the circumferentially oriented roughness with the cortex of the femur neck adjacent the resected surface, as well as even further promote the osseointegration process.

[0015] According to an embodiment of the invention, the frusto-conical proximal section is provided with a screw thread profile similar to that of the proximal cylindrical section.

[0016] According to preferred embodiments of the invention, the frusto-conical proximal section has a screw thread profile of a height less than the screw thread profile of the proximal cylindrical section. Preferably, the height of the screw thread profile on the frusto-conical proximal section is no greater than 0.3 mm (microthreads), more preferably in the range 0.1-0.25 mm, and even more preferably approximately 0.2 mm.

[0017] According to another embodiment of the invention, the frusto-conical proximal section is provided with circumferential beads of a height less than the screw thread profile of the proximal cylindrical section. Preferably, the height of the beads is no greater than 0.3 mm, more preferably in the range 0.1-0.25 mm, and even more preferably approximately 0.2 mm.

[0018] According to preferred embodiments of the invention, the intraosseous anchoring structure is dimensioned such that that the distal end of the anchoring structure projects through the lateral cortex of the femur when the intraosseous anchoring structure is in the anchored position. This arrangement, together with the inventive features of having a frusto-conical proximal section at the proximal end of the anchoring structure, provides a strong anchorage of the anchoring structure in the cortical bone tissue of the femur.

[0019] Advantageously, the intraosseous anchoring structure further has a screw threaded, distal cylindrical section, which extends from the distal end of the intraosseous anchoring structure towards the proximal cylindrical section. The diameter of the distal cylin-

drical section is less than the diameter of said proximal cylindrical section. Preferably, the screw thread profiles of the proximal and distal cylindrical sections are essentially the same.

[0020] According to an embodiment of the invention, the intraosseous anchoring structure further comprises a tapered connecting section provided between the proximal and distal cylindrical sections. This tapered connecting section interconnects the proximal and distal cylindrical sections and, preferably, has a frusto-conical shape which at one end has a base diameter essentially equal to the diameter of said proximal cylindrical section, and at the other end has a top diameter essentially equal to the diameter of said distal cylindrical section.

[0021] The provision of a tapered connecting section would radically reduce any stresses that might be induced by a sharp, step-wise transition between the cylindrical sections of differing diameters. Further, insertion of the fixture would be facilitated, the short and long term stability of the fixture would be improved, as well as the process of osseointegration between the fixture and the surrounding bone tissue.

[0022] Advantageously, the proximal end of the tapered connecting section has essentially the same diameter as the proximal cylindrical section. Likewise, the distal end of the tapered connecting section advantageously has essentially the same diameter as the distal cylindrical section.

[0023] According to preferred embodiments of the invention, the diameter of the first cylindrical section is adapted to the actual size and shape of the femur of the particular patient for whom the femur fixture is intended. Thus, the diameter of the first cylindrical section can vary considerably. However, the diameter of the second cylindrical section is preferably dimensioned to be within a short, limited range. Thus, the flank angle of the connecting section may vary in dependence of the actual dimensions of the first and second cylindrical sections.

Preferably, the flank angle can be varied in the range of 10°-50°, and more preferably in the range of 20°-40°. Preferably, the tapered connecting section is at least partly provided with a roughened surface. This would even further promote the osseointegration process at the transition area between the cylindrical sections. The roughened surface could be achieved through blasting, preferably grit-blasting, etching, or the like. Alternatively or additionally, the surface of the tapered proximal section is provided with a circumferentially oriented roughness, for instance in the form of circumferential beads or screw threads. The height of the beads or screw threads is preferably no greater than 0.3 mm, more preferably in the range of 0.1-0.25 mm, and even more preferably approximately 0.2 mm.

[0024] According to an embodiment of the invention as hereinafter described, the tapered connecting section is at least in part provided with one or more self-tapping cutting recesses.

[0025] According to preferred embodiments of the present invention, femur fixture further comprises a head section. The head section is provided with a collar abutting the tapered proximal section, which collar delimits the insertion of the femur fixture into bone tissue. Preferably, the surface of the collar facing the proximal section is inclined inwardly so as to mate with a resected bone tissue surface that has been given a correspondingly inclined shape. Preferably, the angle of inclination is within the range of 10°-20°, preferably approximately 15°. Alternatively, the surface of the collar facing the proximal section is given a concave shape, so as to mate with a convex bone tissue surface. Thereby, an improved contact between the femur fixture and the bone surface can be obtained.

[0026] Preferably, said collar surface is provided with radially spaced circular beads or grooves for increasing the stability of the inserted femur fixture and promote the osseointegration between the femur fixture and the bone tissue. Preferably, these beads have a height

in the range of 0.1-0.5 mm, preferably in the range of 0.2-0.4 mm, and even more preferably approximately 0.3 mm.

[0027] According to a preferred embodiment the present invention there is further provided a set of femur fixtures according to the invention with the frusto-conical proximal section and the proximal cylindrical section of each fixture in the set having different dimensions, whereby the fixture in the set having the frusto-conical and cylindrical sections of correct size for abutting the cortex of the femur neck of a patient can be selected for use in that patient.

[0028] According to a preferred embodiment of the invention, there is further provided a set where the frusto-conical proximal section and the proximal cylindrical section of each fixture in the set have different dimensions, while the dimension of the distal cylindrical section is essentially the same for all fixtures in the set. Thereby, the fixture in the set having the frusto-conical and cylindrical sections of correct size for abutting the cortex of the femur neck of a particular patient can be selected for use in that patient.

[0029] Further scope of applicability of the present invention will become apparent from the detailed description given hereinafter. However, it should be understood that the detailed description and specific examples, while indicating preferred embodiments of the invention, are given by way of illustration only, since various changes and modifications within the spirit and scope of the invention will become apparent to those skilled in the art from this detailed description.

Brief Description of the Drawings

[0030] The present invention will become more fully understood from the detailed description given hereinbelow and the accompanying drawings which are given by way of illustration only, and thus are not limitative of the present invention, and wherein:

[0031] Fig. 1 is a perspective view of a femur fixture for a hip-joint prosthesis in accordance with an embodiment of the invention~~,~~;

[0032] Fig. 2 is an opposite perspective view of the femur fixture shown in Fig. 1,

[0033] Fig. 3 is a longitudinal side view of the femur fixture~~,~~;

[0034] Fig. 4 is a longitudinal sectional view of the femur fixture~~,~~;

[0035] Fig. 5 is an enlarged fragmentary sectional view showing the tapered proximal section and the head of the femur fixture~~,~~;

[0036] Fig. 6 is a bottom view of the femur fixture~~,~~;

[0037] Fig. 7 is a fragmentary sectional view of the collum of the human femur~~,~~; with a cavity formed therein for reception of the femur fixture~~,~~; ~~and~~

[0038] Fig. 8 is a fragmentary sectional view of the collum of the human femur, with the femur fixture inserted therein~~,~~;

[0039] Fig.9 is a perspective view similar to Fig. 2 of the femur fixture with a roughened surface which is at least partially blasted;

[0040] Fig. 10 is a perspective view similar to Fig. 9 of the femur fixture with a connecting section having circumferential beads;

[0041] Fig. 11 is a longitudinal side view similar to Fig. 3 of the femur fixture with a connecting section having a screw thread profile;

[0042] Fig. 12 is a longitudinal sectional view similar to Fig. 4 of the femur fixture with a connecting section having the screw profile;

[0043] Fig. 13 is a longitudinal side view similar to Fig. 11 of the femur fixture with a connecting section have circumferential beads; and

[0044] Fig. 14 is a perspective view similar to Fig. 10 of the femur fixture with a connecting section having a screw thread.

Description of Exemplary Embodiment

[0045] With reference to Figs 1-8, there is shown an integrally formed femur fixture 1 for a hip-joint prosthesis preferably made from commercially pure titanium and consisting of (i) an intraosseous anchoring section 3 of circular cross-section, and (ii) a head section 5. The anchoring section 3 is intended for insertion laterally into a cavity 30 of complementary profile (Fig. 7), said cavity 30 being drilled into the neck of a femur through a resected section 33 made by resection of the head of the femur. The head section 5 of the fixture, which will protrude from the resected section 33 when the intraosseous anchoring section 3 is located in the cavity 30 (Fig. 8), is arranged for supporting a ball 25 of the hip-joint prosthesis which interacts with the anatomical acetabular cavity or an acetabular part of the hip-joint prosthesis where a total hip-joint prosthesis is required.

[0046] As can be seen in Figs 1-3, the intraosseous anchoring section 3 has proximal and distal cylindrical sections 11, 13 of different outer diameter, with the diameter of the proximal cylindrical section 11 being greater than that of the distal cylindrical section 13. The intraosseous anchoring section 3 further has a tapered terminal distal section 12, contiguous with the distal cylindrical section 13, a frusto-conical connecting section 15 connecting the proximal cylindrical section 11 to the distal cylindrical section 13, and a frusto-conical proximal section 18 connecting the proximal cylindrical section 11 to the head section 5.

[0047] The proximal cylindrical section 11 presents a screw-threaded outer surface for screwing into an outer bone cavity section 32 of said cavity. The distal cylindrical section 13 also presents a screw-threaded outer surface, for screwing into a narrow drilled hole 31,

which is coaxial with said outer cavity section 32. The screw-threads of the proximal cylindrical section 11 have the same pitch and height as those of the distal cylindrical section 13.

[0048] The major diameters of the screw threads on the proximal and distal cylindrical sections 11, 13 are sized to be greater than the inner diameter of complementary cylindrical sections of the outer cavity section 32 and the drilled hole 31 provided in the cavity 30 of the femur neck (See Fig. 7). Accordingly, the intraosseous anchoring section 3 is able to be anchored in the cavity 30 by screwing of the femur fixture 1 into the cavity 30, with the screw threads on the proximal and distal cylindrical sections 11, 13 threading into the bone tissue in the boundary wall of the cavity 30.

[0049] As seen in Fig. 8, the diameter of the proximal cylindrical section 11 is in fact sized such that the threads thereon register in the peripheral layer of cortical bone 34 in the femur neck, as outlined in WO93/16663 and WO97/25939. The threads on the proximal cylindrical section 11 are thus secured in the stronger cortical bone 34 as opposed to the spongier cancellous bone 35, thereby giving the femur fixture 1 greater fixation in the femur neck. Due to the fact that the femur dimensions can vary from patient to patient, the diameter of the proximal cylindrical section can vary in the range from approximately 16-26 mm (cf. Figs 3 and 8).

[0050] As illustrated in Fig. 8, the axial length of the intraosseous anchoring section 3 is such that in the anchored position of the intraosseous anchoring section 3, the distal end 12 thereof projects through the lateral cortex 34 of the femur.

[0051] With reference to Figs 3-5, the frusto-conical proximal section 18 also has threads thereon. The height of these threads is 0.2 mm (so-called microthreads) which is less than that of the threads on the proximal and distal cylindrical sections 11, 13. Further, the frusto-conical proximal section 18 is sized so that the microthreads engage with the cortex 34 of the

femur neck at the resected surface. In the embodiment described herein, the frusto-conical terminal proximal section 18 has a flank angle of approximately 12°, and an axial extent of approximately 8 mm.

[0052] The distal diameter of the proximal section 18 is adapted to the diameter of the neighbouring proximal cylindrical section 11, such that there are no sharp edges in the transition area between the frusto-conical proximal section 18 and the proximal cylindrical section 11. Consequently, the proximal diameter of the frusto-conical proximal section 18 is in the range of approximately 20-30 mm.

[0053] The diameter of the distal cylindrical section 13 does not have to be varied in dependence of the femur dimensions of the patient. The diameter of the distal cylindrical section 13 is approximately 11 mm, or within the range of 10-12 mm.

[0054] The frusto-conical connecting section 15 interconnects the proximal and distal cylindrical sections 11, 13 to one another. In this embodiment, the diameters at the respective end of the connecting section 15 correspond to the diameters of the proximal and distal cylindrical sections 11, 13, respectively. In other words, the distal end of the connecting section 15 has essentially the same diameter as the distal cylindrical section 13, and the proximal end of the connecting section 15 has essentially the same diameter as the proximal cylindrical section 11.

[0055] As a result of the fact that the diameter of the proximal cylindrical section 11 can be varied between different femur fixtures, while the diameter of the distal cylindrical section 13 is not varied, the dimensions of the connecting section will be varied in accordance with the varying difference in diameter between the proximal cylindrical section 11 and the distal cylindrical section 13. Since the axial extent of the connecting section is kept relatively short, i.e. within the range of approximately 7.5-10.5 mm, the flank angle of the connecting section

can vary from approximately 20° for the narrowest fixture alternative, up to approximately 37° for the widest fixture alternative.

[0056] In the herein described embodiment of the invention, the surface of the frusto-conical connecting section 15 is provided with a grit-blasted surface for promoting the osseointegration between the surface and the surrounding cancellous bone tissue. The surface could also, or alternatively, be provided with a screw thread profile for promoting said osseointegration and improve the anchorage of the femur fixture 1. As a further alternative, the frusto-conical connecting section 15 may be left smooth, even polished.

[0057] As can be seen in figs 2 and 3, bridging the boundary between the proximal cylindrical section 11 and the frusto-conical connecting section 15 are a series of equi-spaced, circumferentially-arranged, sharp-edged cutting recesses or notches 14 for self-tapping into a pre-cut outer bone cavity section 32. The cutting recesses 14 each communicate with a channel 16 in the proximal cylindrical section 11 for autologous transplantation of the bone cut by the cutting recesses 14 as the femur fixture 1 is screwed into the bore in the femur neck, as detailed in WO97/25939.

[0058] Further, bridging the boundary between the distal cylindrical section 13 and the tapered terminal distal section 12 are also a series of short, sharp-edged circumferentially-arranged cutting recesses 17 for the distal cylindrical section 13 to be self-tapped into said drilled, relatively narrow hole 31.

[0059] With reference to Figs 1, 7 and 8, the head section 5 of the femur fixture 1 has a collar section 20 and a tapered mounting section 23 for the ball component 25 of the hip-joint prosthesis to be mounted on. The mounting section 23 is provided with a recess 24 for reception of the ball component 25. The collar section 20 delimits the insertion of the intraosseous anchoring section 3 into the bore in the femur neck by abutting with the resected femur sec-

tion 33 adjacent the opening to the cavity 30. As can be seen in Fig. 5, the distal surface 21 (Fig. 5) is inclined inwardly for mating with a correspondingly inclined bone surface of the resected femur section 33 (Fig. 7). The angle of inclination in the embodiment herein described is approximately 15°. Further, as seen in Fig. 6, for improved anchorage and osseointegration, the distal surface 21 of the collar section 20 is provided with radially spaced, circumferential beads 22, said beads having a height of approximately 0.3 mm.

[0060] The surgical procedures described in WO93/16663 and WO97/25939 for implanting the femur fixtures disclosed therein can also be adapted for implantation of the femur fixture 1 and as such are incorporated herein by reference.

[0061] The anchorage of the femur fixture 1 is primarily reliant on the registration of the threads in the bone of the femur, principally the registration of the threads on the proximal cylindrical section 11 in the cortex 34 of the femur neck and the registration of the threads on the distal cylindrical section 13 in the lateral cortex 34 of the femur. This is in distinction to femur fixtures which rely on a thrust plate mechanism for their fixation, for example as in GB-A-2033755.

[0062] The femur fixture 1 herein described with reference to the accompanying figures can be varied in numerous ways within the scope of the invention. For instance, the femur fixture 1 could be in the form of an assembly in which the component parts are assembled (i) for insertion thereof laterally into the bore as a one-piece structure, as disclosed in WO93/16663, or (ii) by connecting the parts together in the bore, as disclosed in WO93/01769. The femur fixture 1 could also be made from any biocompatible material of strength sufficient to withstand the loads imposed upon it in situ.

[0063] Turning now to Fig. 9 an embodiment of the femur fixture is shown with a connecting section 15a having a roughened surface which is at least partly a blasted surface.

In Fig. 10, a connecting section 15b is shown having a roughened surface 15 which is at least partly provided with a circumferentially oriented roughness in the form of circumferential beads that have a height less than that of the screw thread profiles of the first and second cylindrical sections and no greater than 0.3 mm.

[0064] In Figs. 11 and 12, a connecting section 15c is shown having a roughened surface which is at least partly provided with a circumferentially oriented roughness in the shape of a screw thread profile that has a height less than that of the screw thread profiles of the first and second cylindrical sections and no greater than 0.3 mm. Fig. 13 illustrates a proximal section which is provided with a roughness 18a in the form of circumferential beads. In Fig. 14, a connecting section 15d is illustrated having a roughened surface which is at least partly provided with a circumferentially oriented roughness in the shape of a screw thread profile that has a height essentially the same as that of the screw thread profiles of the first and second cylindrical sections.

[0065] It will be appreciated that the invention has been described with reference to an exemplary embodiment and that the invention can be varied in many different ways within the scope of the appended claims. For instance, the implant is not confined to use as a femur fixture for a hip-joint prosthesis. As an example, the implant could take the form of a bone fixation screw. It will further be appreciated that the use in the appended claims of reference numerals from the Figures of drawings is for the purposes of illustration and not to be construed as having a limiting effect on the claims.

ABSTRACT OF THE DISCLOSURE

A femur fixture ~~(1)~~ for a hip-joint prosthesis comprising an intraosseous anchoring structure ~~(3)~~ of a generally circular cross-section for screwing laterally into a complementary bore drilled laterally into the neck of a femur after resection of the femur head to an anchored position. The intraosseous anchoring structure ~~(3)~~ has a proximal end, a distal end, a relatively short frusto-conical proximal section ~~(18)~~ at the proximal end, and a proximal cylindrical section ~~(11)~~ having a screw thread profile thereon. The proximal cylindrical section ~~(11)~~ extends from the frusto-conical proximal section towards the distal end of the anchoring structure ~~(3)~~. The frusto-conical proximal section ~~(18)~~ and the proximal cylindrical section ~~(11)~~ each being dimensioned so as to bear against the cortex of the femur neck when the intraosseous anchoring structure ~~(3)~~ is in the anchored position.

~~———~~The invention also relates to a set of such femur fixtures, wherein the frusto-conical proximal section ~~(18)~~ and the proximal cylindrical section ~~(11)~~ of each fixture ~~(1)~~ in the set have different dimensions, whereby the fixture in the set having the frusto-conical proximal section ~~(18)~~ and the proximal cylindrical section ~~(11)~~ of correct size for abutting the cortex of the femur neck of a particular patient can be selected for use in that patient.